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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,289	01/02/2004	Syed F.A. Hossainy	50623.363	2385

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,289	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,40,42-50 and 65-67* is/are pending in the application.

4a) Of the above claim(s) *39,40 and 42-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 8/17/2006.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (USPN 5,824,049). Ragheb discloses a coated implantable medical device comprising a primer layer, a bioactive (i.e. drug) layer, and a porous layer, wherein the primer layer is posited onto the surface of the medical device (i.e. between the drug layer and the surface of the device) (abstract; figure 1; column 11, lines 1-5). Ragheb discloses that the medical device is preferably a stent (column 5, lines 1-3). Ragheb also discloses polymers including monoacrylates, cyanoacrylates, polyacrylonitrile, polyvinyl acetate and photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule such as trimethylopropane triacrylate (columns 11-12). Ragheb's disclosure of polymers including photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule reads on polyester diacrylates. Ragheb discloses that the bioactive material may be deposited by a variety of methods, for instance, a

particularly convenient method is to apply a mixture of the bioactive and a fluid and then allowing the fluid to evaporate leaving the bioactive deposited as a layer (column 17, lines 42-55). Ragheb also discloses that the bioactive may be deposited as microencapsulated particles, dispersed in liposomes, adsorbed onto or absorbed into small carrier particles as well as depositing monodispersed polymeric particles to the device comprising one or more bioactive materials (column 18, lines 20-24 and 55-63). It should be noted that the examiner is giving the claims the broadest most reasonable interpretation and as currently written the reservoir region is claimed as "the reservoir layer comprising a drug dispersed in the reservoir layer". There are no other elements required such as a polymer. Ragheb's disclosures therefore render the claims anticipated.

Response to Arguments

4. Applicant's arguments filed 8/17/2006 have been fully considered but they are not persuasive. Applicant's argue that:

a. Ragheb does not teach a reservoir layer comprising a drug dispersed in the reservoir layer,

b. Ragheb fails to teach unsaturated polymers.

In response to argument a, Ragheb discloses that the bioactive material may be deposited by a variety of methods, for instance, a particularly convenient method is to apply a mixture of the bioactive and a fluid and then allowing the fluid to evaporate leaving the bioactive deposited as a layer (column 17, lines 42-55). Ragheb also

discloses that the bioactive may be deposited as microencapsulated particles, dispersed in liposomes, adsorbed onto or absorbed into small carrier particles as well as depositing monodispersed polymeric particles to the device comprising one or more bioactive materials (column 18, lines 20-24 and 55-63). It should be noted that the examiner is giving the claims the broadest most reasonable interpretation and as currently written the reservoir region is claimed as "the reservoir layer comprising a drug dispersed in the reservoir layer". Currently, there are no other elements required such as a polymer. Ragheb clearly teaches several embodiments that have a drug is dispersed in the bioactive layer (i.e. reservoir layer) with or without a polymer. Thus, the examiner respectfully disagrees with applicant's position and the rejection is therefore maintained.

In response to argument b, it is the position of the examiner that the term unsaturated polymers can be interpreted to include any polymer that is unsaturated, that is any polymer that includes, for example, a double bond. There is no teaching in applicant's specification that an unsaturated polymer is specifically defined as one that has a saturated backbone and Ragheb teaches various "unsaturated" polymers that include, for example, double bonds (cols 11-12). Also, Ragheb does not specify what the monomers in question are polymerized/reacted with nor does Ragheb teach the ratio of such ingredients. Thus, it is not appropriate to assume that said monomers will produce "saturated" polymers. For these reasons, the examiner finds applicant's remarks are unpersuasive. Thus, the rejections over Ragheb are maintained.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Independent claim 65 and its depending claims 66 and 67 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A reservoir layer comprising a polymer is a critical or essential element to the practice of the invention. However said polymer is not included in the claim(s) and the lack thereof is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims are drawn to an implantable medical device comprising a coating, wherein the coating comprises a reservoir layer and a primer region; the reservoir layer comprises a drug dispersed in the reservoir layer. Applicant's specification (pages 18-21) describes the reservoir layer comprising a polymer that is made by combining a polymeric compound and a solvent or a combination of solvents. Once the polymer and solvent(s) are mixed, an active ingredient/drug is added. The mixture is then applied to the device (over the primer region) and the solvent evaporates, leaving behind the reservoir region comprising the polymer and drug dispersed therein. Therefore after careful review of applicant's specification, it is the position of the examiner that the reservoir layer requires a polymeric carrier for the drug to be dispersed in and subsequently coated on the medical device.

7. Independent claim 65 and its depending claims 66 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reservoir region comprising a polymer and a drug dispersed therein, does not reasonably provide enablement for a reservoir region comprising a drug dispersed therein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant's specification (pages 18-21) describes the reservoir layer comprising a polymer that is made by combining a polymeric compound and a solvent or a combination of solvents. Once the polymer and solvent(s) are mixed, an active ingredient/drug is added. The mixture is then applied to the device (over the primer region) and the solvent evaporates, leaving behind the reservoir region comprising the polymer and drug dispersed therein. Applicant's specification does not describe any other possible embodiment regarding the reservoir region, such as a drug and solvent mixed together in the absence of a polymer. One of ordinary skill in the art could envisage that once a drug/solvent solution is applied to a medical device that the drug would then be dispersed in the reservoir region. Since the specification does not describe such an invention, it is the position of the examiner that the instant specification is not sufficient to support the generic concept of a reservoir region comprising a drug dispersed therein.

Pertinent Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reich et al. (USP 5,962,620) teaches several configurations of multilayer coatings for the use in stents that include primer regions and drug regions comprising a drug and a polymer (i.e. reservoir regions) as well as the specific polymers polyisocyanates, polyether polyurethanes and di and trifunctional acrylates.

Conclusion

9. All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

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